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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,626	06/05/2001	Johanna Jacoba Maria Meulenberg	4041.1US	9761

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EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/874,626	MEULENBERG ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,7,10,14-22,25 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,7,10,14-22,25 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/04/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed April 9, 2004 in response to the Office Action of August 27, 2004 is acknowledged and has been entered. Claims 6, 11-13 and 26 have been cancelled. Claims 5, 7, 10, 14-22, 25 and 27-31are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, February 4, 2004, is attached to the instant Office Action.

Drawings

The Office acknowledges the receipt of the corrected drawings.

Claim Rejections - 35 USC § 102

The rejection of claims 25 and 30 under 35 U.S.C. 102(b) as being anticipated by Wensvoort et al. (WO 92/21375) **is withdrawn** in view of Applicant's amendment.

The rejection of claims 29 and 31 under 35 U.S.C. 102(b) as being anticipated by Wensvoort et al. (WO 92/21375) **is maintained** for reasons of record.

The instant invention is drawn to a cell culture contain an RNA virus genome of PRRSV recombinant or a recombinant nucleic of an PRRSV. Recombinant nucleic acid can be interpreted to mean sequences from different sources or manipulating the sequences in any way

by well-known laboratory techniques. The claims are drawn to compositions, the product-by-process steps are not given weight.

Wensvoort et al. teaches the nucleic acid sequence of Leystad virus (LV) which belongs to the order *Nidoviralis* (see figure 1). The references has deposited the virus (CDI-NL-2.91) in the process of isolating the virus the virus was passaged in cells in the petri dish which indicates that the virus was transcribed *in vitro*. The limitation of "*in vitro*" transcription can be read broadly to include viral production by passaging the virus in a cell culture in a petri dish. Limitation from the specification are not read into the claims. The genome of LV is 14.5 to 15.5 in length (see page 7, lines 15-22). Claim 4 of the Wensvoort et al. reference is drawn to a composition of matter comprising a recombinant vector derived from the LV. Therefore, the instant invention is anticipated by Wensvoort et al

The rejection of claims 29-31 under 35 U.S.C. 102(b) as being anticipated by Moormann et al. (Journal of Virology 1996) **is withdrawn** in view of Applicant's amendment to the claims.

Claim Rejections - 35 USC § 103

The rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over Wensvoort et al. (WO 92/21375) in view of Moormann et al. (Journal of Virology 1996) **is withdrawn** in view of Applicant's amendment to the claim.

The rejection of claims 7, 10, 14-22 and 27-31 under 35 U.S.C. 103(a) as being unpatentable over Wensvoort et al. (WO 92/21375) in view of Moormann et al. (Journal of

Virology 1996) **is maintained** for reasons of record, claims 29-31 have been added to the instant rejection as the amendments indicate that the RNA virus is a PRRSV virus.

Applicant's arguments have been fully considered but fail to persuade. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In this instance, the reference of Wensvoort et al. teaches the nucleic acid sequence of Leystad virus (LV) which belongs to the order *Nidoviralis* (see figure 1), all 15088 nucleotides. Having taught the entire PRRSV genome, the refence teaches both coding and noncoding strands of the DNA structure as the sequences was made from a DNA even though the figure only depicts one strand. The reference has deposited the virus (CDI-NL-2.91) in the process of isolating the virus the virus was passaged in cells in the petri dish which indicates that the virus was transcribed *in vitro*. The limitation of *in vitro* transcription can be read broadly to include viral production by passaging the virus in a cell culture in a petri dish. The genome of LV is 14.5 to 15.5 in length (see page 7, lines 15-22). Claim 4 of the Wensvoort et al. reference is drawn to a composition of matter comprising a recombinant vector derived from the LV. The reference also teaches that the attenuated vaccines can be made by serially passaging the LV in lung macrophages of other species, or in other cell systems, or in other animals until the virus has lost the pathogenicity. The process of attenuation causes the virus to mutate which indicates that the virus has been genetically modified, the modification can occur at any point along the viral genome.

The reference of Moormann et al. teaches *in vitro* transcribing cDNA from a positive stranded RNA virus to produce an infectious clone in the test tube. The reference also teaches replacing the ORF of one virus with the ORF of another strain of virus. Replacing these heterologous nucleic acid sequences produces a virus that can be used as a vaccine, and this vaccine virus can be distinguished from a natural infection by the different antigens it presents. The reference does not teach making an infectious clone of PPRSV.

The claims are drawn to compositions, in product-by-process claims the process steps are not given process weight as the patentability of the product are not dependent on the process. Therefore the claim limitations of the host cells used in the process steps, *in vitro* transcription step are not given weight.

It remains the position of the office that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the cDNA taught by Wensvoort et al. and apply the *in vitro* method taught by Moorman et al. to produce an infectious RNA particle. One of ordinary skill in the art would have been motivated to use an *in vitro* transcribed virus, for the purpose of vaccination because the composition is completely defined. The artisan would know exactly what is in the composition that is being injected into the animal. One of ordinary skill in the art would have been motivated to produce a vaccine that contains heterologous sequences in order to have a marker that can distinguish vaccinated from naturally infected animals. There is a high expectation of success in producing a replication competent virus when exchanging coding sequences from closely related viruses. Therefore, the instant invention is obvious over Wensvoort et al. in view or Moormann et al.

Claim Rejections - 35 USC § 112

The rejection of claims 5-7, 10-12, 14-22, 25, 27-31 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention **is withdrawn** in view of Applicant' amendment to the claims.

Claim Objections

The objection of claims 26 **is withdrawn** in view of Applicants cancellation of the claims.

Double Patenting

The rejection of claims 5-7 and 10-22 and 25-31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,268,199 **is withdrawn** in view of Applicant's filing of a terminal disclaimer.

New Objections in view of Applicants amendments:

Claim Rejections - 35 USC § 112

Claims 5 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rejected because it is not entirely clear how much of the genetic sequence must be deleted in order to met the instant claim limitation. Claim 5 has the

limitation of "lacking genetic information in any one of ORF....." and claim 25 has the limitation of "but lacking genetic information encoding an envelope protein". It is not clear how much of the genome is lacking clarification is required.

The following suggestion are made for clarification purposes:

Claim 5: An isolated recombinant nucleic acid of a Porcine Reproductive and Respiratory Syndrome virus (PRRSV) comprising an *in vitro* transcribed RNA of a cDNA copy of a PPRSV genome with a deletion of the entire ORF selected from any of ORF 1a, 1b and 2-7.

Claim 25: A complementary DNA to a Porcine Reproductive and Respiratory Syndrome virus (PRRSV) genome with a deletion of the entire envelope protein encoding region.

The above are mere suggestions for potential clarification of the claim language. Applicant is reminded that any amendment to the claims must be supported by a written description in the specification; it is applicant's obligation to ensure the proper support is indeed present. This is to serve as a warning that the suggestions made by the examiner have not been checked for support in the specification.

Conclusion

Claims 5, 7, 10, 14-22, 25 and 27-31 are rejected.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on February 4, 2004 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PHD.
PATENT EXAMINER 5/28/04